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CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			VU, QUYNH-NHU HOANG	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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## DETAILED ACTION

### *Response to Amendment*

Amendment and Request for Continued Examination (RCE) filed on 05/13/10 have been entered.

Claims 16-21, 22-33, 35-36 are present for examination.

Claims 1-15, 21 and 34 are cancelled.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 16-20, 22, 24, 29-33, 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable by Webster, Jr. (US 5,057,092) in view of Fish (US 5,006,291).**

**Regarding claim 16, 33, 35-36,** Webster discloses a catheter comprising: an elongate shaft 12 including an inner polymer layer 22 defining a lumen of the elongate shaft; a reinforcement layer (including 24, 26, 28) disposed about the inner polymer layer, and an outer polymer layer 30 disposed about the reinforcement layer, the reinforcement layer comprising a tubular braid having a first helical member 24 interwoven with a second helical member 26, and a plurality of axial members 28 disposed between the first helical member and the second helical member in some of plurality of crossover points but not each of the plurality of crossover points as in claim 16.

As seen in Figs. 2 or 5, the plurality of axial members 28 are attached at the distal end of inner layer 22 and the proximal end of inner layer 22 (not shown); the axial members 28 are free and movable in between the first and second helical members 24 and 26. Therefore, the plurality of axial members 28 are not fixed to the inner polymer layer and the outer layer such that the plurality of axial members are moveable relative to the inner polymer layer and the outer polymer layer.

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Fish discloses a reinforced plastic tubing comprises a first helical member 26 interwoven with a second helical member 28, and a plurality of axial member 29 disposed between the first helical members 26 and the second helical member 28 at each of the plurality of crossover points, see Fig. 4.

*Applicant also admitted that if the axial members 34 were positioned under or over the helical members 32A and 32B, the inner layer 38 or the outer layer 30 may become fixed to the axial members 34, thereby limiting relative movement and flexure there between...By positioning the axial members 34 between the helical members 32A and 32B, relative movement there between is permitted thereby maintaining some amount of flexibility. See pg 13, lines 6-13 of Specification.*

*Similarly, Fish suggests the arrangement of first, second helical members and the axial members are same as the claimed invention. Therefore, the pluralities of axial members are not fixed and movable to maintain some amount of flexibility.*

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster with a interwoven cross construction, as taught by Fish, in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility.

However, Webster further discloses that the workers skill in the art and technology to which this invention pertains will appreciate the alterations and changes in described apparatus can be practiced without meaning fully departing from the principals spirits and scope of the his invention (col. 4, lines 17-22).

It would have been an obvious matter of design choice to provide the axial member with different arrangement such as disposed between the first and second helical member at each of the plurality of cross over point. Therefore, it appears that the invention would perform equally well with device of Webster.

**Regarding claim 17**, the axial members are uniformly spaced about the circumference to the shaft.

**Regarding claims 18-19**, Webster in view of Fish discloses the claimed invention (see rejection above). Webster in view of Fish does not clearly show that four axial members are uniformly spaced apart by 90° about the circumference of the shaft; eight axial members are uniformly spaced apart by 45° about the circumference of the shaft. It would have been an obvious matter of design choice to provide the axial members as listed above, since applicant has not disclosed that the number of axial members spaced apart

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by 45° or 90° solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device of Webster.

**Regarding claim 20**, Webster discloses, in Fig. 1, the elongate shaft includes a proximal portion and a distal portion, and wherein the distal shaft portion has fewer axial members 28 than the proximal shaft portion.

Furthermore, it is noted that those skilled in the art will recognize that if an inner diameter of the proximal shaft is larger than an inner diameter of distal shaft portion will give the same result that the distal shaft portion has fewer axial members than the proximal shaft portion.

**For example, Head (US 6,148,865) is one of evidence shows that the distal shaft portion has fewer the axial members 22 the proximal shaft (see Fig. 3A); or Osborne (US 5,251,640) shows that the distal shaft portion has fewer the axial members 12 the proximal shaft (Figs. 1-5).**

Not only that, the cross section area or diameter of distal portion of catheter is smaller than proximal portion is very well-known in the catheter art for easy to manipulate or insert into the body.

It would have been an obvious matter of design choice to provide the axial members as listed above, since applicant has not disclosed that the number of axial members solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device of Webster.

**Regarding claims 22 and 24**, the first and second helical members each comprise polymer material (col. 2, lines 54-65).

**Regarding claim(s) 29-32**, they encompass the same scope of the invention as to that of claims 16-19 above except they are drafted in method format instead of apparatus format. The claim(s) is/are therefore rejected for the same reason as set forth above.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*,

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11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent Nos. 6,709,429.

Claims 16, 22-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-9, 11, 13-28 of U.S. Patent Nos. 6,942,654.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the device and method of instant claims are fully disclosed and covered by the claims in the U.S. patents. 6,709,429 and 6,942,654.

### ***Response to Arguments***

Applicant's arguments filed 05/13/10 have been fully considered but they are not persuasive..

1. Applicant argues that nowhere Webster or Kaye discloses that the plurality of axial members are not fixed to the inner polymer layer and the outer polymer layer such that the plurality of axial members are movable relative to the inner polymer layer and the outer polymer layer".

In response, please see new ground rejection of Webster in view of Fish above for more details.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

/Quynh-Nhu H. Vu/  
Examiner, Art Unit 3763